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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/014,846 | 12/14/2001 | Mark G. Torchia | 22163-3001 | 1835 |

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EXAMINER

JUNG, WILLIAM C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3768

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/014,846

Applicant(s)

TORCHIA ET AL.

Examiner

William Jung

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40,41,43-56,79,80,83-88 and 92-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57-62,64,66-78, and 89-91 is/are allowed.
- 6) ☒ Claim(s) 40,41,43-56,79,80,83-88 and 92-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed March 6, 2006 have been fully considered but they are not persuasive.

After further consideration of the applicant's argument along with the added limitation regarding cross-sectional area being 200 to 250 times larger than the supply duct, examiner respectfully disagrees in obviousness. Although the scope of the limitation is clearly defined or changed from the previous claim in claims 40 and 79, the obviousness of the limitation is still defined in combination of teachings in Diederich and Heiner. Neither Diederich or Heiner specifically disclose the ratio of the cross-sectional area to the supply duct of the cooling chamber however, the critical factor the surface ratio as defined above do not distinguish from the teachings in Diederich and Heiner. The critical feature of the expansion of cooling fluid in Diederich and Heiner is that the chamber itself must expand to achieve the desired temperature of the therapeutic device. In Diederich, this critical temperature for low heat is less than 45°C, which encompasses the temperature range (zero to 25°C) in claims 41 and 80. Therefore, regardless of the surface ratio defined above, the end result of the temperature range is obvious in view of Diederich and Heiner. Therefore, examiner maintains the previous rejection with new argument based on the same prior art from the office action dated September 7, 2005 and repeated below.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3768

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 40, 41, 44-56, 79, 80, 83-88, and 92-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Diederich* (US 5,620,479) in view of *Heiner* (US 6,551,274 B2).

Diederich substantially discloses all claimed features in claims 40, 41, 43-56, 79, 80 and 82-95

Claims 40, 43, 51, 52, 55, 79, 82, and 94: Diederich discloses of an ultrasound therapy method and apparatus, where a catheter 12 is designed to place in a living body, invasively placing the catheter to a therapeutically targeted volume. Once the catheter is placed in a desired volume, an HIFU is applied to the targeted tissue to perform therapeutic procedure where the catheter includes distal end with ultrasound transducers 16 providing heat directed that the target volume (col. 3, lines 11-67; col. 6, line 43 – col. 7, line 35). The shape of the transducer is cylindrical or disk like with probe rotation to cover different angle to the treatment volume (col. 12, line 48- col. 13, line 2). In addition, the catheter consists of thermocooling mechanism to remove heat from the probe by circulating pressurized fluid around the heating transducer (col. 3, line 66 – col. 4, line 62). However, Diederich does not explicitly teach that the return duct has a larger cross-sectional area than the supply duct. The deficiency in Diederich's teaching is supplemented in Heiner where an ablation catheter has an expandable cooling chamber with return duct having larger cross-sectional area that the supply duct (see figure2). Neither Diederich or Heiner specifically disclose the ratio of the cross-sectional area to the supply duct of the cooling chamber however, the critical factor the surface ratio as defined above do not distinguish from the teachings in Diederich and Heiner. The critical feature of the expansion of

cooling fluid in Diederich and Heiner is that the chamber itself must expand to achieve the desired temperature of the therapeutic device. In Diederich, this critical temperature for low heat is less than 45°C, which encompasses the temperature range (zero to 25°C) in claims 41 and 80. Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Heiner's expandable cooling chamber with Diederich's device described above to provide more efficient cooling mechanism.

Claims 53, 54, 92, and 93: Diederich also discloses of temperature sensor to generate temperature representation of the heating zone during the therapeutical procedure (col. 4, lines 54-col. 5, line 3).

Claims 50, 56, and 95: Diederich discloses of heat sources consisting of laser or optical light source to direct the thermal control of the heating elements (col. 1, line 60 – col. 2, line 6).

Claims 41, 44-49, 80, and 83-88: The cooling mechanism described above is further disclosed by Diederich as having cooling fluid circulating the transducer with cooling chamber, air for liquid to improve the heating distribution and controlling the heating temperature. The air duct or spacer 22 is arranged inside the outer tube where the tube is supplying heat removal from the transducer (col. 7, line 57 – col. 8, line 7).

Allowable Subject Matter

4. Claims 57-62, 64, 66-78, and 89-91 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 12, 2006

Eleni Mantis-Mercader
ELENI MANTIS-MERCADER, SPE
ART UNIT 3768